



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/319,541	08/19/1999	RAINER H. MULLER	62-659-50781	3247

20736 7590 11/19/2003
MANELLI DENISON & SELTER
2000 M STREET NW SUITE 700
WASHINGTON, DC 20036-3307

EXAMINER

SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
----------	--------------

1617

DATE MAILED: 11/19/2003

LS

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/319,541

Applicant(s)

MULLER, RAINER H.

Examiner

Shahnam Sharareh

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9,25 and 31-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9,25 and 31-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 8, 2003 has been entered.

Amendments filed on August 8, 2003 have been entered. Claims 9, 25, 31-52 are pending. Claims 37, 38, 44, and 51-52 are independent. Claims 37-38, 51-52 are directed to product. Claim 44 is directed to a process.

Any rejection that is not addressed in this Office Action is considered obviated in view of persuasive arguments.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.

Art Unit: 1617

(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(f) BRIEF SUMMARY OF THE INVENTION.

(g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).

(h) DETAILED DESCRIPTION OF THE INVENTION.

(i) CLAIM OR CLAIMS (commencing on a separate sheet).

(j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

In the instant specification none of the heading appears to be present. t

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 44-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 44 recites the limitation of "suspending and dissolving the excipient phase and matrix material in a liquid to form a suspension." This limitation is ambiguous, because if the excipient phase and the matrix material are dissolved in a liquid, they form a solution, not a suspension.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 9, 31-35, 38, 40, 44-46, 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al US Patent 5,202,159.

The independent claim 44 and dependent claims thereof are directed to methods of preparing formulations comprising suspending and dissolving a matrix material phase, and an excipient phase in a liquid, and spray drying the suspension. The independent claim 38 is directed to formulations in the form of particles consisting essentially of an excipient and a matrix forming material prepared by a spray-drying product.

Chen discloses methods of preparing sodium diclofenac enteric coated microcapsule powder comprising dissolving sodium diclofenac (active substance) in water to form a solution, then add an amount of excipient to the solution to form a suspension, then add Eudragit L 30D (an acrylic polymeric moiety encompassed by the instant polymers) to the suspension, and finally atomize the slurry to form spray-dried powder (see abstract, col. 8-lines 26-55). Therefore, Chen meets all limitations of the instant method claims.

Chen formulates his powder by using the same components as instantly claimed, in the same concentrations via the same process steps; namely spray drying (see col 4, table I, item V). Chen further shows that the microcapsule powders obtained by his method show a compressibility index of about 50% (see table II, line 43). Chen's powder inherently possesses the same coherency characteristics as instantly claimed formulations, because Chen uses the same precursor compounds and method steps to formulate his powder as instantly claimed formulations. Thus, Chen anticipates the limitations of the instant product claims.

Applicant's arguments in the response filed on August 8, 2003 have been fully considered but are not found persuasive. Applicant argues that Chen's compositions are not compressible. But contrary to such statement, Chen discloses powder microcapsules that possess a 50% compressibility index. Further, Applicant has not provided any evidence showing the contrary. Finally, the recitation of "wherein the matrix material-containing compound is directly compressible into larger units or tablets without requiring binder," is viewed to be an inherent property of the matrix material so long as they are the same as the prior art.

Claims 9, 25, 31-43, 51-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Takada et al US Patent 5,561,990.

Takada teaches microparticles comprising a polymer containing a drug and a preventing aggregation agent (col 2, lines 30-65) for various pharmaceutical compositions such as oral or injectable formulations (col 9, lines 55-58, col 10, lines 48-56). Takada employs aggregation-preventing agents such as mannitol or lactose (col 2,

Art Unit: 1617

lines 55-60; example 3). The polymer used by Takada includes polyacrylates and cellulose derivatives (col 6, lines 61-66). Takada also teaches the use of fatty acid ester as suitable polymeric moieties. (see col 7, lines 7-13). Takada employs water as a solvent (col 11, lines 45-50). Takada's particles contain all elements of the instant claims and are prepared by spray drying methods. Thus, they inherently meet all functional characteristics of the instant particles.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 31-40, 43-52 rejected under 35 U.S.C. 103(a) as being unpatentable over JP 01-151518 (JP '518).

JP '518 discloses folic acid composition powder that is produced by spray-drying a dispersion of folic acid suspension. JP '518 states that the suspension formed before spray drying can contain polymers such as polyvinylpyrrolidone, cellulose derivatives

Art Unit: 1617

such as ethylcellulose or hydroxypropylcellulose, and/or lactose. The JP '518 also provides the use of water as a solvent and further indicates that the ultimate particle size is within a 80 micron range. The abstract of JP '518 does not state whether the suspension of folic acid prior to spray-drying contains a polymer, cellulose derivative or lactose.

Nevertheless, it would have been obvious to one of ordinary skill in the art at the time of invention to add any such components to the suspension of folic acid during the process and prior to spray drying step and formulate the powders containing a polymer, or a cellulose derivative in combination with lactose for their known intended use, because as suggested by the JP '518, such ingredients may be utilized and the ordinary skill in the art would have had a reasonable expectation of success in using them.

Furthermore, even though JP '518 does not explicitly teach the amount of cellulose derivatives, it would have been obvious to one of ordinary skill in the art at the time of invention to optimize such measurements by routine experimentations.

Claims 9, 25, 31-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP '518 in view of Takada et al US Patent 5,561,990.

JP does not specifically teach the use of acrylic or fatty acid polymers in its suspension.

Takada teaches that such polymeric moieties are successfully used in preparing microparticles possessing prolong release activity. (col 6, lines 20-38). Takada also characterizes PVAs and acrylic acid polymers as art equivalents (see col 62-67).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to substitute PVP of JP '518 with acrylic or fatty acid polymeric moieties of Takada, because the ordinary artisan would have had a reasonable expectation of success in improve prolong release properties of JP particles.

Information Disclosure Statement

The information disclosure statement filed Nov 13, 2002 fails to comply with 37 CFR 1.97(d) because it lacks the fee set forth in 37 CFR 1.17(p). It has been placed in the application file, but the information referred to therein has not been considered. See MPEP 609.


Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.


RUSSELL TRAVERS
PRIMARY EXAMINER